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| APPLICATION NO. | 1 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
|---|------|-------------|----------------------|-------------------------|-------------------------|--|
| 09/841,363 | _ | 04/24/2001 | Lawrence L. Labuda | 4785.2US | 6854 | |
| 24247 | 7590 | 05/30/2006 | | EXAMINER | | |
| TRASK B | | | NAGPAUL, JYOTI | | | |
| P.O. BOX 2550 SALT LAKE CITY, UT 84110 | | | | ART UNIT | PAPER NUMBER | |
| , . | | | | 1743 | • | |
| | | | | DATE MAILED: 05/30/2000 | DATE MAILED: 05/30/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|--|--|--|--|--|--|
| Office Action Summers | 09/841,363 | LABUDA ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| The MAN INC DATE of this country is | Jyoti Nagpaul | 1743 | | | | |
| The MAILING DATE of this communication a Period for Reply | ppears on the cover sneet wi | th the correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR of after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perior - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNION (1.136(a). In no event, however, may a red will apply and will expire SIX (6) MON (oute, cause the application to become AB | CATION. eply be timely filed THS from the mailing date of this communication. EANDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 13 | <u>March 2006</u> . | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ Th | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| closed in accordance with the practice under | Ex parte Quayle, 1935 C.D | . 11, 453 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4) ⊠ Claim(s) <u>1-38</u> is/are pending in the application 4a) Of the above claim(s) is/are withdrest solutions 5) □ Claim(s) is/are allowed. 6) ⊠ Claim(s) <u>1-38</u> is/are rejected. 7) □ Claim(s) is/are objected to. 8) □ Claim(s) are subject to restriction and solutions | rawn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examin 10) The drawing(s) filed on is/are: a) acceptable and applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examin 11). | ccepted or b) objected to be drawing(s) be held in abeyant ection is required if the drawing | ce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents. 2. Certified copies of the priority documents. 3. Copies of the certified copies of the priority application from the International Bure. * See the attached detailed Office action for a list | nts have been received. nts have been received in A iority documents have been au (PCT Rule 17.2(a)). | pplication No received in this National Stage | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) | 4) ☐ Interview 9 | summary (PTO-413) | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/06 Paper No(s)/Mail Date | Paper No(s | s)/Mail Date nformal Patent Application (PTO-152) | | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 24-30 and 36-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 24-30 recites a structural limitation, the definition of which is dependent upon a particular assembly of the transducer to a particular respiratory flow component. Since no flow component is recited as an element of the claims, this structural definition is ambiguous.

Each of claims 36-37 recites a structural limitation the definition of which is dependent upon a particular assembly of the transducer to a particular respiratory flow component. With respect to instant Claim 36, applicant recites, "and being substantially stable for a period of at least about eight hours", it highly ambiguous as to what the structural element is with respect to the flow component. With respect to Claim 37, applicant recites "the detector has a stability of about ±2 torr over eight hours at an atmospheric oxygen concentration", it highly ambiguous as to what the structural element is with respect to the flow component.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 6. Claims 1-10, 13-15, and 17-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al ('658) in view of Knodle et al ('720).

Stanley et al disclose a transducer for measuring oxygen in an airway breathing tube which comprises, referring to Figure 2, a light source (27), photodiode detector (28), a signal processor (23) and a luminescent oxygen sensor film (25). In operation, the sensor film is illuminated by the light source so as to excite fluorescent emission.

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The fluorescence is quenched quantitatively by oxygen present in the tube (14), and is measured by the detector. The transducer of Stanley et al differs from the claimed invention in that it fails to specify that it is removably securable to the breathing tube. However, Knodle et al disclose a similar optical sensor transducer for measuring carbon dioxide in a breathing tube. Knodle et al specifically disclose the transducer as being removably securable to breathing tubes (column 11, lines 34-45). It would have been obvious to one of ordinary skill in the art to removably secure the transducer of Stanley et al to an associated breathing to in order to facilitate replacement thereof, as per the teaching of Knodle et al.

Regarding instant claim 2, Stanley et al provide a processor in the form of an amplifier and recorder in communication with the detector (Figure 1). Regarding instant claim 3, see Stanley et al at column 3, lines 16-18). Regarding instant claim 5, see Figure 4 of Stanley et al recognizing a non-linear response over a broad range of oxygen concentrations. As such, it would have been obvious to one of ordinary skill to apply a different mathematical processing to lower range concentrations as compared with higher range concentrations. Regarding instant claims 8 and 9, see Stanley et al at column 3, lines 12-15). Regarding instant claim 10, Stanley et al teach a calibration mechanism at column 5, lines 59 et seq. Stanley et al further teach excitation bands that encompass the visible spectrum (column 3, lines 12-15), and the particular wavelengths presently claimed.

Regarding instant claims 17-19, it is noted that while Stanley et al teach measurement of oxygen in a breathing tube, Knodle et al teach optical measurement of

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carbon dioxide in a breathing tube. Knodle et al teach such detection utilizing an infrared source. Thus, it would have been obvious to one of ordinary skill in the art to modify the transducer of Stanley et al to further include an infrared light source to enable detection of both oxygen and carbon dioxide.

Regarding instant claims 20-23, see optical filters (16 and 17) disclosed by Stanley et al in Figure 2. Regarding instant claims 24-30, see Stanley et al at the paragraph bridging columns 4 and 5, recognizing sensor susceptability to temperature variations. In view of such recognition, it would have been obvious to one of ordinary skill in the art to modify the device of Stanley et al to include a temperature regulation device, in order to maintain the sensing film at a desired, optimal operating temperature.

Regarding instant claims 31-34, it is noted that the presently claimed features are clearly provided by the structure depicted by Stanley et al in Figures 1 and 2.

7. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Yafuso et al ('172).

The transducer of Stanley et al further differs in that it fails to provide a beam divider and reference detector. However, Yafuso et al teach such a structure in an optical detector for the purpose of accomodating variations in the excitation light. It would have been obvious to one of ordinary skill in the art to so modify the transducer of Stanley et al in order to attain the known benefits thereof, as per the teaching of Yafuso et al.

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8. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Hauenstein et al ('727).

Hauenstein et al disclose an optical sensor for determination of oxygen through fluorescence quenching. Hauenstein et al further teach that a signal to noise ratio is enhanced by use of a pulsed excitation signal. It would have been obvious to one of ordinary skill in the art to so modify the transducer of Stanley et al in order to attain the known benefits thereof, as per the teaching of Hauenstein et al.

- 9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as background information related to applicant's field of endeavor.
- 10. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Alcala et al.

The transducer of Stanley et al further differs in that it fails to provide a signal processor that receives the signal from the detector and outputs a modified signal with a phase angle corresponding to a decay time of an excited luminescent composition of the respiratory flow component. Alcala et al teaches the decay times characteristics of a response signals. It would have been obvious to one of ordinary skill in the art to so modify the transducer of Stanley et al in order to further obtain lifetimes of the luminescent composition.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jyoti Nagpaul whose telephone number is 571-272-1273. The examiner can normally be reached on Monday thru Friday (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JN

Supervisory Patent Examiner
Technology Center 1700